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Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Paper No. 52

Serial Number: 08/078,768

Filing Date: June 16, 1993

Appellant(s): Tullis

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Kenneth A. Weber

For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the reply brief filed on July 3, 1996. The reply brief has been entered even though it is not limited to a discussion of issues and points of argument that are newly brought to the record by the Examiner's Answer.

Appellant identifies five new points of argument in the Examiner's Answer of April 30, 1996 and responds to the new ground of rejection.

The following are in response to the five new points of argument identified by Appellant.

1. Appellant asserts that the Examiner's Answer raises a new issue by pointing out that the brief is inaccurate in connection with whether there are reasons in the record for the PTO's position taking into account the declarations of Drs. Schwartz and Ruth. The reasons for the PTO's position on this matter are clear and are set forth in the record, so they will not be repeated here. Appellant's argument confuses the presence of reasons with Appellant's disagreement with the conclusion reached by the Examiner. This disagreement is not new to this record. Appellant further makes much of whether a literature search would be needed by one of skill in the art given the instant application and the degree of undue experimentation that might be needed. That such a search would be needed is not at issue since the Examiner and Appellant agree that it would (e.g., see response filed July 20, 1995 and

reference thereto on page 13 of the Examiner's Answer).

The point of the rejection is, and always has been, the deficiencies in the instant application in teaching those of skill in the art how to practice the invention. Finally in this regard, there is no argument by the Examiner that a *per se* rule of any type be adopted or applied.

2. On the meaning of colorable, the meaning of the term is no clearer to the Examiner even in view of pages 4-6 of the Reply Brief. However, this is unimportant to the arguments and disposition of the issues.
3. It is noted that Appellants do not rely on post filing date references Exhibits A-E.
4. The comment about point 6 in the response of July 20, 1995 (see Examiner's Answer, page 14) is not a new argument because Appellants made reference to those reasons in at least one location in the Brief (e.g., top of page 15). Appellant now complains that a counting error was made and that the Examiner made much of same and is "focusing the Board's attention on an irrelevant counting error." Evidence for these conclusions is lacking. The Examiner's Answer merely

identifies point 6 and identifies point 6 as opinion rather than objective reason. The rest of Appellant's response about this asserted new point deals with issues that are not new and so will not be responded to here, the record being sufficient.

5. Appellant asserts that the fact that the inventor has not provided a declaration under Rule 132 is a new point of argument raised in the Examiner's Answer. The Examiner's Answer merely summarizes the record on this point. No declaration had been or is asked for. The Examiner agrees with Appellant that the statements made by the inventor and alluded to in the record are clear, but this is not a new issue.

The following are in connection with Appellant's discussion of the new ground of rejection. Appellant makes four arguments.

1. Appellants first urge that the Gura and Rojanasakul references are irrelevant (Reply Brief, pages 9-13). Appellant argues that these references are irrelevant because they are concerned with clinical applications of antisense technology. This argument is not convincing because the references are not limited to clinical applications and because the references were

cited to support the difficulties with antisense technology that have been at issue throughout the file history of the instant application. For example, the PTO position has long been that real problems exist in connection with stability of oligonucleotides, entry of oligonucleotides into cells, and targeting of stabilized forms of oligonucleotides (e.g., see the Office action mailed December 16, 1992, page 3). At page 11 of the Reply Brief, Appellant asserts that the Rojanasakul reference supports Appellant's position in that Rojanasakul refers to work that apparently used increased concentrations of oligonucleotides to achieve the desired antisense effect in a given system.

Appellant then quotes from Rojanasakul. That this section of the reference supports Appellant's notion that the instant application enables one of skill in the art to practice the claimed invention cannot be concluded because Appellant points to no part of the application that would lead one of skill in the art to the same solution alluded to in Rojanasakul and because the realization that came "soon" according to the portion of Rojanasakul quoted by appellant actually

came in 1990 (see reference [47] cited in Rojanasakul).

This is a full nine years after the effective filing date of the instant application. Thus, Appellant argues that a realization that took eight or nine years in a very active field would have taken one of skill in the art only routine experimentation with the benefit of the instant application without saying what the instant application supplies that the rest of the art lacks. Thus, Appellant's argument is not convincing. Appellant further argues that Gura is not a peer reviewed article, but was written by a reporter. Appellant characterizes a simple question in the text as "silly hyperbole." This is not seen as either silly or hyperbole, but a valid question as to the mechanism of action of new drugs. One can infer little or nothing about the mechanism of action of a drug from the fact that clinical trials are underway. Appellant's derogatory remarks in connection with the source of the article are given no weight at all. Appellant has not offered any rebuttal to the substance of the Gura article. Finally, appellant asserts,

"To deny Dr. Tullis patent protection for

his inventive method of downregulating protein simply because he failed to enable the cure for cancer is wrong. It is as wrong as denying an inventor a patent for carrying water in a bucket because the bucket will not function without undue experimentation in the weightless vacuum of the moon."

Appellant is reminded that the purpose of a Reply Brief is to rebut new arguments and/or new rejections in the Examiner's Answer. There is no old or new rejection that is based on a lack of an enabled cure for cancer. Indeed, the Examiner is unaware of the appearance of the word cancer or anything to do with it in any Office action in this record. Second, the force of gravity on the surface of the moon is about one-sixth that at the surface of the earth (no reference cited here, Official notice is taken).

2. Appellant cites three new references with post-filing date publication dates. These references have not been considered because Appellants may not rely on art published after the filing date to complete the enablement of the claimed invention. Appellant then



asserts once more (page 15 of the Reply Brief) that the mechanism of the claimed invention does work as has been asserted all along by Appellants. This assertion is thus not new, and the discussion of the Rojanasakul and Gura references in the Examiner's Answer is adhered to.

3. Appellant asserts that if the Rojanasakul and Gura references are considered, then so should Appellant's post filing date references be considered. To reiterate, post-filing date references may not be used to complete a non-enabled application, yet post-filing date references may be used as evidence to provide insight as to the state of the art at a particular point in time. Since the Examiner has cited references that show that even several years after the effective filing date of the invention, many groups of skilled artisans were struggling with at least three of the problems outlined by the PTO early in the prosecution history of this application (i.e., stability, uptake, and targeting), it is reasonable to conclude that the instant application, which does not provide guidance to those of skill in the art in how to overcome these

difficulties, does not enable one of skill in the art to practice the invention.

4. Appellants objected to the late presentation of Gura and Rojanasakul as references. Neither of these references could have been cited earlier because Gura was published in October of 1995 and Rojanasakul was published in 1996.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

  
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